

K072606

**Toshiba America Medical Systems, Inc.**  
**510(k) Pre-market Notification; Aquilion ONE TSX-301A/2**

**510(k) Summary**

**OCT 2 \* 2007**

**Date:** September 12, 2007

**Submitter's Name:** Toshiba America Medical Systems, Inc.

**Submitter's Address:** P.O. Box 2068, 2441 Michelle Drive,  
Tustin, CA 92781-2068

**Submitter's Contact:** Paul Biggins, Director Regulatory Affairs  
(714)730-5000

**Establishment Registration Number:** 2020563

**Device Proprietary Name:** TSX-301A/1, Aquilion ONE CT System, k063189  
TSX-101A/h, /I Aquilion 32/64 SP CT System,  
k051833

**Common Name:** Scanner, Computed Tomography, X-Ray  
[Fed. Reg. No. 892.1750, Pro. Code: 90JAK]

**Regulatory Class:** II (per 21 CFR 892.1750)

**Performance Standard:** 21 CFR Subchapter J,  
Federal Diagnostic X-ray Equipment Standard

**Predicate Device(s):** TSX-301A Aquilion ONE CT System

**Reason For Submission** Modification to existing device

**Description of this Device:**

The TSX-301A/2 is a whole body CT scanner. This device captures cross sectional volume data sets. The device consists of a gantry, patient couch (table) and peripheral cabinets used for data processing and display.

**Summary of Intended Uses:**

This device is intended to produce cross sectional volume sets of the anatomy. Additionally the system, when used by a trained professional, is capable of providing data for dynamic and perfusion studies of organs and extremities.

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**Technological Characteristics:**

This device employs similar materials and processes as found in the predicate device. The device produces ionizing radiation that is employed to generate cross sectional images of the anatomy.

**Safety and Effectiveness Concerns:**

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR § 1020.30 and 1020.33, that apply to this upgrade, will be met and reported via a supplement to the initial report for the predicate device. Additionally this system is in conformance with the applicable parts of the IEC 60601-1 {applicable portions}; IEC 60601-2-32, and IEC 60601-2-44. - Medical Device Safety standards.

**Substantial Equivalence:**

This device is similar in materials and processes to that of the predicate device, Toshiba TSX-301A Aquilion ONE CT scanner.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Toshiba America Medical Systems, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

OCT 2 2007

Re: K072606  
Trade/Device Name: TSX-301A/2, Aquilion ONE CT System  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: September 14, 2007  
Received: September 17, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

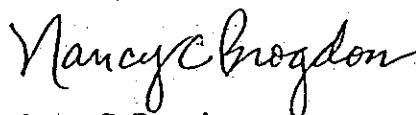
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

|                |                                  |              |
|----------------|----------------------------------|--------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology)          | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology)                      | 240-276-0120 |
| Other          |                                  | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Toshiba America Medical Systems, Inc.  
Pre-Market Notification 510(k) for TSX-301A/2 Aquilion ONE CT System

## Indications for Use

510(k) Number (if known):

Device Name: TSX-301A/2, Aquilion ONE CT System

Indications for Use:

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, pancreas, etc.

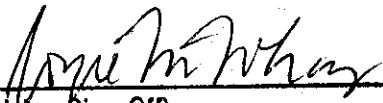
The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can then be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number 5072606